B. PACKAGE LEAFLET

PACKAGE LEAFLET

Please read this leaflet carefully because it contains important information for you. If you have further questions, please ask your doctor or your pharmacist. This medicine has been prescribed for you personally, and you should not pass it on to others.

PRODUCT NAME

Cetrotide 0.25 mg powder and solvent for solution for injection
Cetrorelix (as acetate)

QUALITATIVE AND QUANTITATIVE COMPOSITION
What are the components of Cetrotide 0.25 mg?

One vial with 55.7 mg powder containing as active substance 0.26 - 0.27 mg cetrorelix acetate equivalent to 0.25 mg cetrorelix. Additionally, the powder contains mannitol as excipient.

One pre-filled syringe containing 1 ml water for injections.

MARKETING AUTHORISATION HOLDER AND MANUFACTURER
Who is responsible for the marketing and manufacture of Cetrotide 0.25 mg?

Marketing Authorisation Holder

ASTA Medica Aktiengesellschaft
An der Pikardie 10
01277 Dresden
Germany

Manufacturer

ASTA Medica Aktiengesellschaft
Weismüllerstraße 45
60314 Frankfurt
Germany

PHARMACEUTICAL FORM AND CONTENTS
What does Cetrotide 0.25 mg consist of?

Cetrotide 0.25 mg is a powder for solution for injection. It is available in packs of one or seven vials.

Additionally, for each vial the packs contain

- one pre-filled syringe with solvent (water for injections) for parenteral use for dissolving the powder in the vial
- one injection needle with a yellow mark for injecting the water into the vial and withdrawing the solution from the vial
- one injection needle with a grey mark for injecting the solution
- two alcohol swabs for cleaning purposes.

PHARMACOTHERAPEUTIC GROUP
How does Cetrotide 0.25 mg work?

Cetrotide 0.25 mg inhibits the effects of a natural hormone, called luteinising hormone releasing hormone (LHRH). LHRH regulates the secretion of another hormone, called luteinising hormone (LH), which induces ovulation during the menstrual cycle. Cetrotide 0.25 mg inhibits premature ovulation which is undesirable during hormone treatment for ovarian stimulation as only mature egg cells are suitable for fertilisation.

THERAPEUTIC INDICATIONS
Why use Cetrotide 0.25 mg?

Cetrotide 0.25 mg is used to prevent premature ovulation during a controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques.

In clinical trials Cetrotide 0.25 mg was used with human menopausal gonadotropin (HMG), however, limited experience with recombinant follicle stimulating hormone (FSH) suggested similar efficacy. HMG and FSH are hormones promoting egg maturation.

CONTRA-INDICATIONS
When should you not use Cetrotide 0.25 mg?

Do not use Cetrotide 0.25 mg if you

- are allergic to cetrorelix acetate, mannitol or exogenous peptide hormones (medicines similar to Cetrotide 0.25 mg)
- are pregnant or breast-feeding
- have already reached your menopause
- have a moderate or severe kidney or liver disease.

PRECAUTIONS FOR USE
What precautions have to be taken?

During or following hormonal stimulation of the ovaries an ovarian hyperstimulation syndrome can occur. This event is related to the stimulation procedure with gonadotropins (hormones promoting egg maturation). For symptoms and suitable measures please refer to the Patient Information Leaflet of the gonadotropin-containing medicine prescribed for you.

Luteal phase support (a measure to support the onset of pregnancy) should be given according to the reproductive medical centre´s practice.

There is limited experience up to now with the administration of Cetrotide 0.25 mg during a repeated ovarian stimulation procedure. Therefore you should use Cetrotide 0.25 mg in repeated cycles only after a careful risk/benefit evaluation by your doctor.

SPECIAL WARNINGS
Driving and using machines?

As far as it is known, Cetrotide 0.25 mg does not impair your ability to drive or to operate machinery.

What special precautions should pregnant or breast-feeding women take?

You should not use Cetrotide 0.25 mg if you are already pregnant, or suspect that you might be pregnant, or if you are breast-feeding.

INTERACTIONS

What other products influence the effect of Cetrotide 0.25 mg and what other products can Cetrotide 0.25 mg effect?

Experimental investigations have shown that interactions are unlikely with medications that are metabolised in the liver. However, the possibility of interactions with commonly used medicinal products cannot entirely be excluded.

INSTRUCTIONS FOR PROPER USE

How much of Cetrotide 0.25 mg should you use and how often should you use it?

The following statements apply to Cetrotide 0.25 mg unless otherwise prescribed by your doctor. Please observe these instructions for use, otherwise you will not fully benefit from Cetrotide 0.25 mg.

The contents of one vial (0.25 mg Cetrorelix) are to be administered once daily, at 24 h intervals, either in the morning or in the evening.

Administration in the morning: Treatment with Cetrotide 0.25 mg should begin on day 5 or 6 of ovarian stimulation (approximately 96 to 120 hours after start of ovarian stimulation) with urinary or recombinant gonadotropins and is to be continued throughout the gonadotropin treatment period including the day of ovulation induction.

Administration in the evening: Treatment with Cetrotide 0.25 mg should begin on day 5 of ovarian stimulation (approximately 96 to 108 hours after start of ovarian stimulation) with urinary or recombinant gonadotropins and is to be continued throughout the gonadotropin treatment period until the evening prior to the day of ovulation induction.

How should you use Cetrotide 0.25 mg?

You may self-administer Cetrotide 0.25 mg after appropriate instruction from your doctor.

Cetrotide 0.25 mg is for injection under the skin of the lower abdominal wall, preferably around the navel. To minimise local irritation, please select a different injection site each day.

Dissolve Cetrotide 0.25 mg powder only with the water contained in the pre-filled syringe. Do not use a Cetrotide 0.25 mg solution if it contains particles or if it is not clear.

Before you administer Cetrotide 0.25 mg yourself, please read the following instructions carefully:

1. Wash your hands. It is important that your hands and all items you use are as clean as possible.

2. Lay out on a clean surface everything you need (one vial, one pre-filled syringe, one injection needle with a yellow mark, one injection needle with a grey mark and two alcohol swabs).

3. Flip off the plastic cover of the vial. Wipe the aluminium ring and the rubber stopper with an alcohol swab.

4. Take the injection needle with the yellow mark and remove the wrapping. Take the pre-filled syringe and remove the cover. Put the needle on the syringe and remove the cover of the needle.

5. Push the needle through the centre of the rubber stopper of the vial. Inject the water into the vial by slowly pushing the plunger of the syringe.

6. Leave the syringe on the vial. Gently agitate the vial until the solution is clear and without residue. Avoid forming bubbles during dissolution.

7. Draw the whole contents of the vial into the syringe. If solution is left in the vial, invert the vial, pull back the needle until the opening of the needle is just inside the stopper. If you look from the side through the gap in the stopper, you can control the movement of the needle and the liquid. It is important to withdraw the entire contents of the vial.

8. Detach the syringe from the needle and lay down the syringe. Take the injection needle with the grey mark and remove its wrapping. Put the needle on the syringe and remove the cover of the needle.

9. Invert the syringe and push the plunger until all air bubbles have been expelled. Do not touch the needle or allow the needle to touch any surface.

10. Choose an injection site at the lower abdominal wall, preferably around the navel. Take the second alcohol swab and clean the skin at the injection site. Hold the syringe in one hand. Gently pinch up the skin surrounding the site of injection and hold firmly with the other hand.

11. Hold the syringe as you would hold a pencil, insert the needle completely into the skin at an angle of about 45 degree.

12. Once the needle has been inserted completely, release your grasp of the skin.

13. Pull back gently the plunger of the syringe. If blood appears continue as described in step 14. If no blood appears, inject the solution slowly by pushing the plunger gently forward. After all of the solution is injected, withdraw the needle slowly, applying gentle pressure with the alcohol swab on the skin where the needle was inserted. Withdraw the needle at the same angle as it was inserted.

14. If blood appears, withdraw the needle with the syringe and gently apply pressure to the injection site. Do not use this solution but empty the syringe in a sink. Start again with step 1.

15. Use the syringe and needles only once. Dispose of the syringe and needles immediately after use (put the covers on the needles to avoid injury).

SPECIAL ADVICE

What do you do if you have used too much of Cetrotide 0.25 mg?

Overdosage of Cetrotide 0.25 mg may result in a prolonged duration of action but is unlikely to be associated with acute toxic effects. Therefore, in case of overdosage no specific measures are required.

What to do if you miss a dose?

If you missed to administer Cetrotide 0.25 mg on one day, please contact your doctor immediately and ask for advice.

Ideally Cetrotide 0.25 mg should be administered at 24 hours intervals. But if you missed to administer Cetrotide 0.25 mg at the right time it is no problem to administer this dose at a different time of the same day.

SIDE EFFECTS
What undesirable effects may Cetrotide 0.25 mg cause?

Mild and transient reactions may occur at the injection site like reddening, itching, and swelling.

Occasionally systemic side effects, like nausea and headache have been reported. In addition, a single case of pruritus has been reported during treatment with Cetrorelix..

A severe hypersensitivity reaction, associated with cough, rash and hypotension, was observed in one patient after 7 months of treatment of ovarian cancer with cetrorelix (10 mg/day). The patient recovered completely within 20 minutes. A causal relationship could not be excluded.

Occasionally, stimulation of ovaries with gonadotropins (hormones promoting egg maturation) may lead to a so-called ovarian hyperstimulation syndrome (OHSS). Symptoms like abdominal pain, tension, nausea, vomiting, diarrhoea and breathing difficulties may indicate an OHSS. Please inform your doctor immediately, if you feel such symptoms.

If you notice any unwanted effect not mentioned in this leaflet or if you are unsure about the effect of this medicine, please inform your doctor or pharmacist.

STORAGE INSTRUCTIONS
How long can you keep Cetrotide 0.25 mg?

The Cetrotide 0.25 mg powder in the vial and the solvent in the pre-filled syringe have the same expiry date. It is printed on the labels and on the carton. Do not use the Cetrotide 0.25 mg powder or the solvent after this date.

How long can you keep Cetrotide 0.25 mg after preparation of the solution?

The solution should be used immediately after preparation.

Store the medicine out of the reach of children.

How is Cetrotide 0.25 mg to be stored?

Do not store above 25°C. Keep the container in the outer carton in order to protect it from light.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED
When was this leaflet prepared?

April 1999

If you have any further questions please consult your doctor or pharmacist.

Further information
For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder**.**

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PACKAGE LEAFLET

Please read this leaflet carefully because it contains important information for you. If you have further questions, please ask your doctor or your pharmacist. This medicine has been prescribed for you personally, and you should not pass it on to others.

PRODUCT NAME

Cetrotide 3 mg powder and solvent for solution for injection
Cetrorelix (as acetate)

QUALITATIVE AND QUANTITATIVE COMPOSITION
What are the components of Cetrotide 3 mg?

One vial with 167.7 mg powder containing as active substance 3.12 - 3.24 mg cetrorelix acetate equivalent to 3 mg cetrorelix. Additionally, the powder contains mannitol as excipient.

One pre-filled syringe containing 3 ml water for injections.

MARKETING AUTHORISATION HOLDER AND MANUFACTURER
Who is responsible for the marketing and manufacture of Cetrotide 3 mg?

Marketing Authorisation Holder

ASTA Medica Aktiengesellschaft
An der Pikardie 10
01277 Dresden
Germany

Manufacturer

ASTA Medica Aktiengesellschaft
Weismüllerstraße 45
60314 Frankfurt
Germany

PHARMACEUTICAL FORM AND CONTENTS
What does Cetrotide 3 mg consist of?

Cetrotide 3 mg is a powder for solution for injection. It is available in a pack with one vial.

Additionally the pack contains

- one pre-filled syringe with solvent (water for injections) for parenteral use for dissolving the powder in the vial
- one injection needle with a yellow mark for injecting the water into the vial and withdrawing the solution from the vial
- one injection needle with a grey mark for injecting the solution
- two alcohol swabs for cleaning purposes.

PHARMACOTHERAPEUTIC GROUP
How does Cetrotide 3 mg work?

Cetrotide 3 mg inhibits the effects of a natural hormone, called luteinising hormone releasing hormone (LHRH). LHRH regulates the secretion of another hormone, called luteinising hormone (LH), which induces ovulation during the menstrual cycle. Cetrotide 3 mg inhibits premature ovulation which is undesirable during hormone treatment for ovarian stimulation as only mature egg cells are suitable for fertilisation.

THERAPEUTIC INDICATIONS
Why use Cetrotide 3 mg?

Cetrotide 3 mg is used to prevent premature ovulation during a controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques.

In clinical trials Cetrotide 3 mg was used with human menopausal gonadotropin (HMG), however, limited experience with recombinant follicle stimulating hormone (FSH) suggested similar efficacy. HMG and FSH are hormones promoting egg maturation.

CONTRA-INDICATIONS
When should you not use Cetrotide 3 mg?

Do not use Cetrotide 3 mg if you

- are allergic to cetrorelix acetate, mannitol or exogenous peptide hormones (medicines similar to Cetrotide 3 mg)
- are pregnant or breast-feeding
- have already reached your menopause
- have a moderate or severe kidney or liver disease.

PRECAUTIONS FOR USE
What precautions have to be taken?

During or following hormonal stimulation of the ovaries an ovarian hyperstimulation syndrome can occur. This event is related to the stimulation procedure with gonadotropins (hormones promoting egg maturation). For symptoms and suitable measures please refer to the Patient Information Leaflet of the gonadotropin-containing medicine prescribed for you.

Luteal phase support (a measure to support the onset of pregnancy) should be given according to the reproductive medical centre´s practice.

There is limited experience up to now with the administration of Cetrotide 3 mg during a repeated ovarian stimulation procedure. Therefore you should use Cetrotide 3 mg in repeated cycles only after a careful risk/benefit evaluation by your doctor.

SPECIAL WARNINGS
Driving and using machines

As far as it is known, Cetrotide 3 mg does not impair your ability to drive or to operate machinery.

What special precautions should pregnant or breast-feeding women take?

You should not use Cetrotide 3 mg if you are already pregnant, or suspect that you might be pregnant, or if you are breast-feeding.

INTERACTIONS

What other products influence the effect of Cetrotide 3 mg and what other products can Cetrotide 3 mg effect?

Experimental investigations have shown that interactions are unlikely with medications that are metabolised in the liver. However, the possibility of interactions with commonly used medicinal products cannot entirely be excluded.

INSTRUCTIONS FOR PROPER USE

How much of Cetrotide 3 mg should you use and how often should you use it?

The following statements apply to Cetrotide 3 mg unless otherwise prescribed by your doctor. Please observe these instructions for use, otherwise you will not fully benefit from Cetrotide 3 mg.

The contents of 1 vial (3 mg cetrorelix) are to be administered on day 7 of ovarian stimulation (approximately 132 to 144 hours after start of ovarian stimulation) with urinary or recombinant gonadotropins.

A single dose of Cetrotide 3 mg results in a duration of action of at least 4 days. If the follicle growth does not allow ovulation induction on the fifth day after injection of Cetrotide 3 mg, additionally
0.25 mg cetrorelix (Cetrotide 0.25 mg) should be administered once daily beginning 96 hours after the injection of Cetrotide 3 mg until the day of ovulation induction.

How should you use Cetrotide 3 mg?

You may self-administer Cetrotide 3 mg after appropriate instruction from your doctor.

Cetrotide 3 mg is for injection under the skin of the lower abdominal wall, preferably around the navel.

Dissolve Cetrotide 3 mg powder only with the water contained in the pre-filled syringe. Do not use a Cetrotide 3 mg solution if it contains particles or if it is not clear.

Before you administer Cetrotide 3 mg yourself, please read the following instructions carefully:

1. Wash your hands. It is important that your hands and all items you use are as clean as possible.

2. Lay out on a clean surface everything you need (one vial, one pre-filled syringe, one injection needle with a yellow mark, one injection needle with a grey mark and two alcohol swabs).

3. Flip off the plastic cover of the vial. Wipe the aluminium ring and the rubber stopper with an alcohol swab.

4. Take the injection needle with the yellow mark and remove the wrapping. Take the pre-filled syringe and remove the cover. Put the needle on the syringe and remove the cover of the needle.

5. Push the needle through the centre of the rubber stopper of the vial. Inject the water into the vial by slowly pushing the plunger of the syringe.

6. Leave the syringe on the vial. Gently agitate the vial until the solution is clear and without residue. Avoid forming bubbles during dissolution.

7. Draw the whole contents of the vial into the syringe. If solution is left in the vial, invert the vial, pull back the needle until the opening of the needle is just inside the stopper. If you look from the side through the gap in the stopper, you can control the movement of the needle and the liquid. It is important to withdraw the entire contents of the vial.

8. Detach the syringe from the needle and lay down the syringe. Take the injection needle with the grey mark and remove its wrapping. Put the needle on the syringe and remove the cover of the needle.

9. Invert the syringe and push the plunger until all air bubbles have been expelled. Do not touch the needle or allow the needle to touch any surface.

10. Choose an injection site at the lower abdominal wall, preferably around the navel. Take the second alcohol swab and clean the skin at the injection site. Hold the syringe in one hand. Gently pinch up the skin surrounding the site of injection and hold firmly with the other hand.

11. Hold the syringe as you would hold a pencil, insert the needle completely into the skin at an angle of about 45 degree.

12. Once the needle has been inserted completely, release your grasp of the skin.

13. Pull back gently the plunger of the syringe. If blood appears continue as described in step 14. If no blood appears, inject the solution slowly by pushing the plunger gently forward. After all of the solution is injected, withdraw the needle slowly, applying gentle pressure with the alcohol swab on the skin where the needle was inserted. Withdraw the needle at the same angle as it was inserted.

14. If blood appears, withdraw the needle with the syringe and gently apply pressure to the injection site. Do not use this solution but empty the syringe in a sink.

15. Use the syringe and needles only once. Dispose of the syringe and needles immediately after use (put the covers on the needles to avoid injury).

SPECIAL ADVICE

What do you do if you have used too much Cetrotide 3 mg?

Overdosage of Cetrotide 3 mg may result in a prolonged duration of action but is unlikely to be associated with acute toxic effects. Therefore, in case of overdosage no specific measures are required.

What to do if you miss a dose?

If you missed to administer Cetrotide 3 mg, please contact your doctor immediately and ask for advice.

SIDE EFFECTS

What undesirable effects may Cetrotide 3 mg cause?

Mild and transient reactions may occur at the injection site like reddening, itching, and swelling.

Occasionally systemic side effects, like nausea and headache have been reported. In addition, a single case of pruritus has been reported during treatment with Cetrorelix.

A severe hypersensitivity reaction, associated with cough, rash and hypotension, was observed in one patient after 7 months of treatment of ovarian cancer with cetrorelix (10 mg/day). The patient recovered completely within 20 minutes. A causal relationship could not be excluded.

Occasionally, stimulation of ovaries with gonadotropins (hormones promoting egg maturation) may lead to a so-called ovarian hyperstimulation syndrome (OHSS). Symptoms like abdominal pain, tension, nausea, vomiting, diarrhoea and breathing difficulties may indicate an OHSS. Please inform your doctor immediately, if you feel such symptoms.
If you notice any unwanted effect not mentioned in this leaflet or if you are unsure about the effect of this medicine, please inform your doctor or pharmacist.

STORAGE INSTRUCTIONS

How long can you keep Cetrotide 3 mg?

The Cetrotide 3 mg powder in the vial and the solvent in the pre-filled syringe have the same expiry date. It is printed on the labels and on the carton. Do not use the Cetrotide 3 mg powder or the solvent after this date.

How long can you keep Cetrotide 3 mg after preparation of the solution?

The solution should be used immediately after preparation.

Store the medicine out of the reach of children.

How is Cetrotide 3 mg to be stored?

Do not store above 25°C. Keep the container in the outer carton in order to protect it from light.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

When was this leaflet prepared?

April 1999

If you have any further questions please consult your doctor or pharmacist.

Further information
For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder**.**

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